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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,900	03/08/2007	Reiner Fischer	2400.0410000/VLC/BAH	3603

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
RODRIGUEZ-GARCIA, VALERIE	
ART UNIT	PAPER NUMBER
4161	
MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,900	FISCHER ET AL.	
	Examiner	Art Unit	
	VALERIE RODRIGUEZ-GARCIA	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *6-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

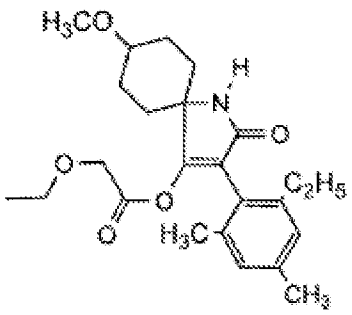
DETAILED ACTION

Status of the Claims

Claims 1-16 are currently pending.

1. Applicant's election with traverse of Group I, claims 1-5, in the reply filed on 07/02/08 is acknowledged. The following elected species is also acknowledged:

(I-b-8):



The traversal is on the ground(s) that Groups I, II and III are related as products, process for manufacturing such and their use (applicant cites 37 CFR 1.475(b)), and that examining these together would not place an undo burden on the Examiner. Applicant argues that the examiner has mischaracterized the technical feature of Group I. Applicant's arguments are not found persuasive because under PCT rule 13.1 a group of inventions should be so linked as to form a single general inventive concept. However, there is lack of inventive concept, due that the spirocyclic pyrrolidin ketoenol core having 2-ethyl-4,6-dimethylphenyl is not consider to be inventive in view of WO01/74770A1 (supplied in the IDS of 02-22-07 and cited in the international search

report). As such, they lack a special technical feature. The examiner here rejoins Group III, claim 8, as is product claim only reciting an intended use.

The requirement is still deemed proper.

Claims 6-7 and 9-16 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07/02/08.

Claims 1-5 and 8 are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Note

The species elected by applicant was not found.

Priority

2. This application is a 371 of PCT/EP04/12644 filed on 11/09/2004, which claims priority benefit of foreign application Germany 103 54 629.4 file on 11/22/2003
This Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

3. Claims 1-5 are objected to because of the following informalities: Independent claim 1 should start with the article, --A--, and dependent claims 2-5 should start with --The--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

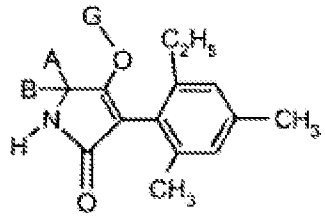
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/74770A1.

The instant claims are drawn to a compound of formula (I),

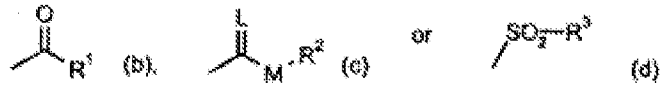


(I)

in which

A, B and the carbon atom to which they are attached represent saturated C_5-cycloalkyl which is optionally monosubstituted by methyl, methoxy or n-propoxy,

G represents one of the groups



in which

L represents oxygen and

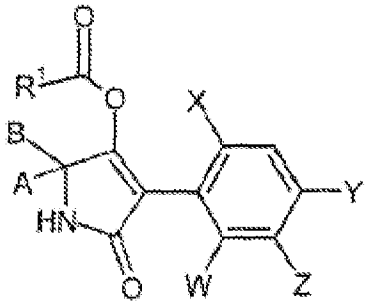
M represents oxygen,

R^1 represents C_1-C_6-alkyl, C_1-C_2-alkoxy-C_1-C_2-alkyl or cyclopropyl,

R^2 represents C_1-C_8-alkyl or C_2-C_6-alkenyl,

R^3 represents C_1-C_4-alkyl.

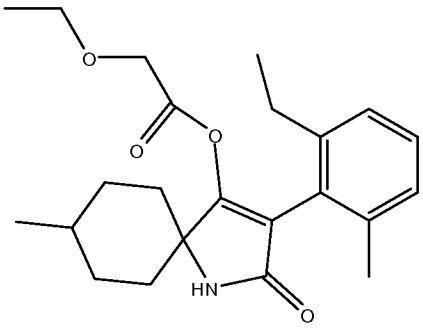
WO 01/74770A1 discloses compounds of the same nature, but with different substitutions in the phenyl ring. W can be H or methyl, Z is H, Y can be H, methyl or ethyl and X can be methyl or ethyl. The prior art does not teach the exact 2,4,6 substitution of the phenyl ring of the instant application.



(I-1-b)

The following compound, in which Y= hydrogen, is compound I-1-b-3 of the prior art (p. 156) and differs from the claimed invention only by a hydrogen on the Y position.

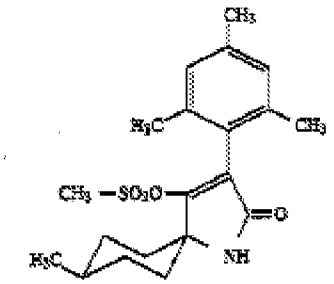
Therefore, the difference between the prior art and the instant application are the length of alkyl chains and the presence of H versus methyl.



It would have been obvious to those skilled in the chemical arts at the time the claimed invention was made to make and use analogs of the compounds of WO 01/74770A1 to produce the instant invention. Analogs differing only in the substitution of hydrogen with methyl, are *prima facie* obvious, and require no secondary teaching. However, the examiner recalls *In Re Herr 134 USPQ 176.* It would be routine for the chemist to insert a methyl group in order to increase lipophilicity. The experienced chemist, who would make applicants' compounds, would be motivated to prepare these compounds on the expectation that structurally similar compounds would possess similar properties and because it is routine nature to perform such experimentation in the art of medicinal chemistry.

5. Claims 1-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patent 5,462,913 in view of Wolff, M.E. *Burger's Medicinal Chemistry 4th Ed. Part I*, Wiley: New York, **1979**, 336-337.

Example (Id-1)



Patent 5,462,913 discloses the compound (col. 51), which differs from the claimed invention by the length of the chain of the substituent on the 2nd position of the phenyl ring. The prior art shows substitution with a methyl while the compounds of the instant application are substituted with an ethyl.

To those skilled in the art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious, because one skilled in the art would have been motivated to prepare homologues of the compounds taught in the reference with the expectation of obtaining compounds which could be used in pharmaceutical compositions. However, the examiner provides Burger's reference.

Wolff teaches that the addition of alkyl groups to active pharmacological agents often improves activity and bioavailability by increasing lipophilicity (see the examples in Table 8.2, p. 337 of a local anesthetic SAR). As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compounds

such as those of Patent 5,462,913, with elongated alkyl groups, as suggested by Wolff, to achieve better bioavailability.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-5 and 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,462,913 in view of Wolff, M.E. *Burger's Medicinal Chemistry 4th Ed. Part I*, Wiley: New York, **1979**, 336-337. See reasoning stated above in the 103 rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VRG

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161